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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,383	01/14/2002	Louis Michael Crowe	660057-2010	5507

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NEW YORK, NY 10151

EXAMINER

EVANSKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,383

Applicant(s)

CROWE ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/17/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-132 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-29, 42-44, 56-59, 67-76, 81-95, 108-110, 122 and 123 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/06 has been entered.

Election/Restrictions

Claims 11-14, 30-41, 45-55, 58-66, 77-80, 96-107, 111-121, and 124-132 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected embodiments, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/10/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 15-29, 42-44, 56-59, 67-76, 81-95-, 108-110, 122, and 123 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original disclosure is the electrical signal selected to induce

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shivering “which increases the subject’s calorie consumption to at least about three times its resting metabolic rate” in combination with the other elements/steps in the claims. The original disclosure did not teach the signal to increase the subject’s calorie consumption to at least about three times its resting metabolic rate, does not teach what the range/limitations of “at least about three times” is, and does not state that its about three times “its resting metabolic rate”. The original disclosure on pages 3 and 10 only describes the signal in terms of “energy usage attainable must be of sufficient intensity that it brings about a cardiovascular training effect in normal subjects, (generally this needs to be above 50% of maximum cardiac output, and preferentially 60 or 70%)” and does not describe the exact limitations of “at least about three times” or the use of a resting metabolic rate. In addition, for claims 42, 56, 93, 108, 122, the specification does not teach stimulating only one muscle to “increase the subject’s calorie consumption to at least about three times its resting metabolic rate”. The original specification on page 21 describes the use of “muscles” to maximize energy usage and weight loss and not just a single muscle. This rejection is related to new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 15-24, 26-29, and 42-44, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minogue et al (WO 00/41764). Minogue states that his device is used to stimulate/contract the muscles (abstract and throughout the specification), specifically the abs and transversalis and oblique muscles (page 24) and different muscles, such as the leg and back muscles (page 32), and uses electrodes sized from 80 to 120 mm by 50 to 150 mm (page 24) and delivers pulses using parameters of 50-1000 microseconds pulse duration, 1-200 Hz, and 0-100 mA (page 25) and pulses where the amplitudes are different (figure 18) and therefore is capable of meeting the functional use recitations in the claims of “so as to induce a shivering phenomenon” and generating a cardiovascular response greater than 50-70% or increases the subject’s calorie consumption to at least about three times its resting metabolic rate since Minogue uses the exact same pulse parameters and electrode sizes as the applicant to cause the muscles to contract. Also, since the pulses are delivered through the same sized electrodes and contain the same pulse parameters, the charge delivered by the Minogue will be the same and meet the claimed charge limitations.

But Minogue does not disclose the monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method of stimulation as taught by

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Minogue, with a monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor since it was known in the art that stimulation systems and methods use a monitor for monitoring a physiological parameter such as heart rate and a feedback mechanism for controlling the signal generator based on the output of the monitor to provide feedback to the signal generator to allow the stimulation to be applied within physiological limits and at a safe level to the patient so the patient does not overexert himself or go outside of the physiological limits.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Minogue et al. Minogue states on page 32 that electrodes can be used on different muscles such as leg muscles and discloses the electrode sizes can be varied on page 24, but does not disclose the length being 190 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode size in the muscle stimulation system as taught by Minogue, with the length of the electrode being 190 mm since it was known in the art that muscle stimulation systems provide longer electrodes, such as being of the length of at least 190 mm, to efficiently stimulate the longer muscles to cause them to contract without causing pain or burning due to the electrical pulse. In addition, Minogue provides a clear suggestion that the electrodes can be modified to vary electrodes to fit the patient and muscle being stimulated. The determination of the most appropriate electrode size by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the medical art.

Response to Amendment

The declaration under 37 CFR 1.132 filed 10/28/05 is insufficient to overcome the rejection of the claims based upon the Minogue reference as set forth in the last Office action

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because: the Minogue reference also discloses the use of his system on the leg and back muscles which would provide calorie consumption to at least about three times its resting metabolic rate. In addition, several claims only state that “a muscle” is stimulated and therefore stimulating the abs and transversalis and oblique muscles would provide the required calorie consumption since these muscles are just as big or bigger than the largest muscle.

Response to Arguments

Applicant's arguments filed 10/11/05 have been fully considered but they are not persuasive. Minogue uses the same pulse parameters and electrode sizes as in the applicants claims. Although Minogue may not use the term “shivering”, “cardiovascular training” or “contractions occurring at 3-12 Hz”, Minogue does (inherently and/or is capable of) perform these functions since he uses the same pulse parameters and electrodes as stated in the applicant's specification and/or claims. The argument that the examiner has not provided any motivation to show that it would have been obvious to include the monitor and feedback into Minogue is not persuasive since the examiner provided the motivation in the 103 rejection. The motivation being “to provide feedback to the signal generator to allow the stimulation to be applied within physiological limits and at a safe level to the patient so the patient does not overexert himself or go outside of the physiological limits”. In addition, the examiner previously provided several references showing this was well known in the art.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

4/14/06

GRE
April 14, 2006

Continuation of Disposition of Claims: Claims withdrawn from consideration are 11-14,30-41,45-55,58-66,77-80,96-107,111-121 and 124-132.